REMARKS

Reconsideration of this application, as amended, is respectfully requested.

Claims 1-16 are pending in the present application.

Of these claims, claims 3, 4, 6 and 9-16 have been withdrawn from consideration.

Claims 1, 2, 5, 7 and 8 are under examination and have been rejected.

With the above amendments, claims 1-7 and 9-16 have been cancelled; claim 8 has been retained.

The Examiner acknowledged Applicant's claim for domestic priority under 35 USC 119(e) (to a provisional application).

The Examiner also acknowledged Applicant's Information Disclosure Statement (PTO-1449) Paper No(s) 3, 4, 5.

ELECTION/RESTRICTION

The Examiner acknowledged Applicant's election with traverse of Group I (claims 1, 2, 5, 7 and 8, each in part) drawn to a method of treating obesity comprising administering a neurotensin-1 agonist to a patient who is or is at risk of becoming obese in Paper No. 8. According to the Examiner, the traversal is on the ground(s) that a search of Group I and Group VII does not constitute a search burden.

The Examiner did not find this persuasive because Group I is drawn to a method of using a neurotensin-1 agonist and Group VII is a pharmaceutical composition of a yet unclear neurotensin-1 agonist and a second compound. The Examiner found that the search and consideration of the "second compound" of Group VII is not only a replication of the search for Group I but also a far more extensive search including several disorders in addition to obesity. Thus, the Examiner concluded that the rejoinder of Groups I and VII constitutes a search burden on the examiner.

Claims 3, 4, 6 and 9-16 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected material; there being no allowable generic or linking claim. The Examiner again acknowledged Applicant's timely traversal of the restriction (election) requirement in Paper No. 8 (30 December 2002); however, the Examiner still considers the requirement to be proper and therefore has made it FINAL.

In order to expedite prosecution of the present application, Applicant hereby confirms the election of Group I (claims 1, 2, 5, 7 and 8, each in part, drawn to a method of treating obesity comprising administering a neurotensin-1 agonist to a patient who is or

is at risk of becoming obese) and withdraws the traverse to the restriction/election requirement. Applicant has canceled the non-elected subject matter, including claims 3, 4, 6 and 9-16, without prejudice to the filing of a divisional application to the non-elected subject matter.

STATUS OF APPLICATION, AMENDMENTS, AND/OR CLAIMS

The Examiner noted that the Preliminary Amendment of Paper No. 8 (30 December 2002) has been entered in full and that claim 11 has been amended. However, as noted above, claim 11 has been canceled without prejudice to pursuing it in a divisional application.

INFORMATION DISCLOSURE STATEMENT

According to the Examiner, the information disclosure statement filed 7 December 2001 (Paper No. 5) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because citation EP 0647629 is not in the English language. The Examiner has stated that this citation has been placed in the application filed, but the information referred to therein has not been considered as to the merits.

Attached hereto is a Supplemental Information Disclosure Statement, which refers to two U.S. patents, which are English language equivalents of EP 0647629. Applicant is sending copies of these references to the Examiner by Express Mail. Applicant respectfully requests that the information referred to in these references be considered on the merits.

CLAIM REJECTIONS – 35 USC §112, FIRST PARAGRAPH

Claims 1, 2, 5, 7 and 8 have been rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. According to the Examiner, claims 1, 2, 5, 7 and 8 are directed to a method of treating obesity comprising administering a neurotensin(-1) agonist or ligand to an obese patient or a patient at risk of becoming obese.

According to the Examiner, the specification asserts that neurotensin receptor ligands or agonists can be used to treat obesity, but provides no nexus between neurotensin receptor (or their ligands/agonists) and obesity. The Examiner stated that the specification provides general guidance regarding drug formulations and assays for neurotensin receptor agonist's activity; however, according to the Examiner, no working

examples have been provided whercin a neurotensin receptor ligands or agonist is administered successfully to treat obesity.

The Examiner found that the breadth of the claims is large. Regarding the term "agent," the Examiner stated that the art recognizes that "agent" can pertain to a wide variety of substances. Therefore, the Examiner concluded that, due to the large quantity of experimentation required to determine how to successfully treat obesity with NT receptor ligands/agonist, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art setting forth the obstacles of treating obesity with NT receptor ligands/agonists, and the large breadth of the claims, undo experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Consistent with the above election/restriction requirement and in order to expedite prosecution of the present application, the claims have been amended to claim 8 for the treatment of obesity using a neurotensin-1 receptor agonist. The term "agent," which appeared in claims 11 and 14, does not appear in these claims. Support for this amendment is in the specification as filed, e.g., at page 2, lines 6-7; and its entry is respectfully requested.

In the specification as filed at page 4, line 28, to page 5, line 22, Applicant has defined the terms used in the present application, including "neurotensin receptor ligand," "neurotensin receptor agonist" and "selective." It is stated in the specification as filed at page 5, lines 23-26, that neurotensin receptor ligands, such as neurotensin-1 receptor agonists, can be identified, for example, by screening a compound library. Methods of identifying agonists and antagonists of receptors are well known to those skilled in the art. Specific procedures that can be used to identify neurotensin receptor ligands, including selective neurotensin-1 receptor agonists, are presented in the specification at page 50, line 5, to page 59, line 25.

In the specification as filed at page 5, line 27, to page 6, line 11, examples of known receptor ligands, including neurotensin and selective neurotensin-1 receptor agonists, are set forth. In fact, in the Boules et al. reference cited by the Examiner, it is known that neurotensin decreases food intake in rats; and it is shown that a novel neurotensin peptide analog decreases food intake and weight in rodents, further showing its use in the treatment of obesity. Applicant has provided further support for the treatment of obesity with the

description of the hosts, dosages and modes of administration in the specification as filed, e.g., at page 6, line 16, to page 12, line 21.

As the Examiner is fully aware, the courts have repeatedly made it clear that the PTO is not the Food and Drug Administration ("FDA"). The only question for the PTO regarding utility is: Is the invention useful? It is for the FDA to determine if human testing is required or even appropriate, with completely different considerations than patentability. Therefore, given Applicants' enabling disclosure, Applicants respectfully requests that this rejection under 35 USC §112, first paragraph, be withdrawn.

Therefore, on the basis of the above amendments and remarks, Applicants respectfully request reconsideration of the present application, as amended, and its early allowance.

Respectfully submitted,

Date: Aug. 27, 2003

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Attachments:
Petition for Extension of Time (2 copies)
Supplemental Information Disclosure Statement

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